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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
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EXAMINER	
BERTAGNA, ANGELA MARIE	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/049,465	ZHENG ET AL.	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *8-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/05; 12/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7, in the reply filed on March 5, 2007 is acknowledged. The traversal is on the ground(s) that since the methods of Group II (claims 8-28) depend from claim 1, the method of Group II cannot be performed with a product materially different from that of Group I. Applicant's argument was not found persuasive, because MPEP 806.05 (h) teaches that a product and process of using the product can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case, as noted previously, the oligonucleotide product of Group I can function in methods materially different from the bDNA assay of Group II. For example, the oligonucleotide of Group I can function as a primer in amplification methods or as a probe in a Northern or Southern blotting method. Since the product of Group I can function in methods materially different from the bDNA method of Group II, the inventions are distinct, and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 5, 2007.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The embedded hyperlinks appear at paragraphs 9, 38, 63, and 80 of the specification. Removal of the "http" would overcome this objection.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter. Claims 1-7 are directed to products of nature, and therefore, are not directed to statutory subject matter. Amendment of the claims to state that the claimed oligonucleotides are "isolated and purified" would overcome this rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (US 5,681,702).

Regarding claim 1, Collins teaches a highly orthogonal six-base universal sequence comprised of four natural bases and two non-natural bases, wherein one to four of the natural bases, arranged in no specific order, are selected from the group consisting of guanosine (G), cytosine (C), adenosine (A), and thymidine (T) or uracil (U) and are separated by one or both of the non-natural bases such that approximately 50% of the sequence is comprised of G/C bases and the sequence has a melting temperature (Tm) of approximately 80-85°C (see Table 7 at column 28, where the oligonucleotide of SEQ ID NO: 31 includes the six-base sequence AFTCCJ, where J is isoguanine and F is isocytosine). Here the four natural bases are A, T, and the two C's, and the two non-natural bases are isoguanine and isocytosine. In the sequence AFTCCJ, two of the natural bases (A and T) are separated from each other by the non-natural base isocytosine. SEQ ID NO: 31 has a G/C content of 44%, which is approximately 50%, and a Tm of 64.2°C, which is approximately 80-85°C (see attached calculation generated using the IDT DNA OligoAnalyzer 3.0).

Regarding claim 2, Collins teaches that the two non-natural bases are isoguanine and isocytosine (see Table 7, where SEQ ID NO: 31 discussed above contains these bases).

Regarding claim 3, as noted above, SEQ ID NO: 31 taught by Collins has a melting temperature of 64.2°C, which is approximately 85°C (see attached calculation generated using the IDT DNA OligoAnalyzer 3.0).

Regarding claims 5-7, SEQ ID NO: 31 of Collins can be used as a universal capture probe to immobilize PCR amplification products to a substrate derivatized with an oligonucleotide complementary to the capture probe. It is noted that the limitations recited in claims 5-7 only recite an intended use for the oligonucleotide and not structural limitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the oligonucleotide of SEQ ID NO: 31 taught by Collins can function as a capture probe to immobilize PCR amplification products on a substrate derivatized with an oligonucleotide complementary to the capture probe, Collins anticipates the instant claims 5-7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (US 5,681,702).

Collins teaches the oligonucleotide of claims 1-3 and 5-7, as discussed above.

Regarding claim 4, the oligonucleotide taught by Collins (SEQ ID NO: 31 in Table 7 at column 28) contains 36 bases rather than the claimed 20-25 bases. Collins also teaches oligonucleotides ranging from 18-41 bases in length (see Table 7 at column 28, where oligonucleotides consisting of 18 bases, 21 bases, 36 bases, and 41 bases are taught).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to optimize the length of SEQ ID NO: 31 taught by Collins. An ordinary practitioner would have recognized this the results-effective variable could be optimized to improve hybridization specificity or the ability to use the oligonucleotide in a multiplex assay with other probes. As noted in MPEP 2144.05 I, "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934

(Fed. Cir. 1990)." In the instant case, the claimed range of 20-25 bases lies within the range of 18-41 bases taught by Collins, and therefore, is prima facie obvious. Also, as noted in MPEP 2144.05 II, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)." Routine experimentation is not inventive, and no evidence has been presented that the selection of the claimed oligonucleotide lengths was other than routine or that the results should be considered unexpected in any way as compared to the closest prior art of Collins. Therefore, in the absence of secondary considerations, the oligonucleotide of claim 4 is prima facie obvious over Collins.

Conclusion

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yang et al. (Biophysical Journal (1998) 75: 1163-1171) teaches a 10-mer containing isoguanine and isocytosine (see page 1164, column 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Art Unit 1637
April 27, 2007

amb

JEFFREY FREDMAN
PRIMARY EXAMINER
5/4/07

Attachments: Exhibit A (2 pages)